IGEL VISIONCARE PTE LTD

JUN 0 4 2002

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510(k) Summary

Submitter Information:

IGEL Visioncare Pte. Ltd.
139 Joo Seng Road, #05-01 ATD Centre
Singapore 368362
Registration Number: 9614154

Contact Person: Mr Stephen D Newman, Chief Executive Officer

Telephone: +65 67491090
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Date Prepared: March 5, 2002

Device Name:

Common Name: Soft (Hydrophilic) Contact Lens

Trade/Proprietary Names: Igel 55 UV (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Igel 55 UV Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Igel 55 UV Toric (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Classification Name: Soft (Hydrophilic) Contact Lens

Device Classification: Class II (21 CFR 886.5925)

Predicate Devices:

The Specialty 55 UV (methafilcon A) Soft (Hydrophilic) Contact Lens, the Specialty 55 UV Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens and the Specialty 55 UV Toric (methafilcon A) Soft (Hydrophilic) Contact Lens were selected as the predicate devices.

The Igel 55 UV lenses are manufactured in the same facility, under the same quality system, using the same moulding, tinting, packaging and sterilization processes. The Igel 55 UV lenses contain the same UV blocking agent as the Specialty 55 UV lenses, and the manufacturing process for adding the UV blocking agent is the same.

Description of Devices:

The Igel 55 UV, the Igel 55 UV Multifocal, and the Igel 55 UV Toric Daily Wear Contact Lenses (methafilcon A) are hemispherical flexible shells which cover the cornea and a portion of the adjacent sclera. The Igel 55 UV Contact Lens is available in a single vision lens design, the Igel 55 UV Multifocal Contact Lens is available in an aspherical lens design, and the Igel 55 UV Toric Contact Lens is available in a back surface toric design. The lens material (methafilcon A) is a hydrophilic

polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid cross-linked with ethyleneglycol dimethacrylate (45.0%) and water (55.0%). A UV absorbing compound has been incorporated into the lens polymer. All lenses are tinted using the color additive Reactive Blue #19.

Comparison to Predicate Device

PARAMETER ***Submission number***	***Igel 55 UV, Igel 55 UV Multifocal, and Igel 55 UV Toric Soft (Hydrophilic) Contact Lenses for Daily Wear***	***Specialty 55 UV, Specialty 55 UV Multifocal and Specialty 55 UV Toric Soft (Hydrophilic) Contact Lenses for Daily Wear*** ***K003526***
Material	methafilcon A	methafilcon A
Material classification	Hydrophilic Lens Group 4	Hydrophilic Lens Group 4
Indication for use	myopia, hyperopia, presbyopia and astigmatism	myopia, hyperopia, presbyopia and astigmatism
Water content	55%	55%
Visible light transmittance	90.3%	90.3%
UV transmittance	< 10%	< 10%
Dk (35° C)	18.9×10^{-11}	18.9×10^{-11}
Powers	+20.00 to -20.00 Diopters	+20.00 to -20.00 Diopters
Color	blue visibility Reactive Blue #19	blue visibility, Reactive Blue #19
Refractive index	1.42	1.42
Specific gravity	1.06	1.06
Method of manufacture	Moulded	Moulded

Indications for Use:

The **Igel 55 UV (methafilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The **Igel 55 UV Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear** is indicated for the correction of presbyopia in myopic and hyperopic eyes in aphakic or not-aphakic persons with non-diseased eyes who exhibit no more than 2.00 Diopters of astigmatism and can obtain satisfactory visual acuity, in a power range of +4.00 to -5.00 Diopters and have near add requirements up to 3.00 Diopters.

The **Igel 55 UV Toric (methafilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 7.00 Diopters.

The lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems. Eyecare practitioners may prescribe the lenses for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems.

Description of Safety and Substantial Equivalence:

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the Igel 55 UV, the Igel UV Multifocal and the Igel 55 UV Toric (methafilcon A) Contact Lenses for Daily Wear. Results of Systemic Injection, Primary Ocular Irritation and Cytotoxicity Tests show the lenses to be non-toxic and non-irritating. Extraction and analysis of the lenses showed no detectable extractables. The Igel 55 UV lenses passed the requirements of sterility and stability testing.

Conclusion:

Information submitted in the 510(k) establishes that the Igel 55 UV, the Igel 55 UV Multifocal and the Igel 55 UV Toric Contact Lenses (methafilcon A) have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that lens properties do not change before the expiration date. Therefore, the devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Stephen D. Newman
Chief Executive Officer
IGEL Visioncare PTE LTD
139 Joo Seng Road #05-01 ATD Centre
Singapore 368362

JUN 0 4 2002

Re: K020855
Trade/Device Name: IGEL 55UV (methafilcon A), IGEL 55UV Multifocal (methafilcon A) and IGEL 55UV Toric (methafilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: March 5, 2002
Received: March 15, 2002

Dear Mr. Newman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS STATEMENT

Device Names:

Igel 55 UV (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K020855